EXHIBIT 47

Anaesthesia, 1997, **52**, pages 1073–1076

APPARATUS

Convection warmers – not just hot air

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Summary

We sought to determine whether the forced air convection warmers (nine Bair Huggers, Augustine Medical, and one Warm Touch, Mallinkrodt Medical) used in our operating theatres could be a source of microbial pathogens. Agar plates were placed directly in the air stream of the warmers. Four of these grew potentially pathogenic organisms. When the warmers were set to blow through perforated blankets, no growth occurred. Three of the warmers were swabbed and sites of colonisation were found in their hoses. After fixing a microbial filter to the end of the hose, organisms were no longer detectable. We conclude that these warming devices are a potential source of nosocomial infection. They should only be used in conjunction with perforated blankets, should have their microbial filters changed regularly and their hoses sterilised. The inclusion of a microbial filter into the nozzle of the hose could be incorporated into the design of the warmer.

Keywords *Equipment*; temperature blankets. *Infection. Hypothermia.*

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Accepted: 3 May 1997

Forced air convection warming devices have revolutionised our management of hypothermia, especially in the operating theatre. They have proved to be very efficient in providing thermal homeostasis during surgery [1, 2]. The maintenance of normothermia has been associated with a reduction in the incidence of postoperative surgical wound infection [3]. Peri-operative hypothermia is also associated with several other complications, including shivering, decreased drug metabolism and clearance, and impaired wound healing [4]. Thus far, studies suggest that convection warming does not increase microbial contamination in the operating room [5, 6].

Convection warmers entrain environmental air through a microbial filter (0.2 μm pore size). The air is heated and blown through a detachable hose. The manufacturers of convection warmers recommend that these devices be used only in conjunction with a specialised blanket with perforations on its underside. They suggest that the filter be changed every 6 months or after 600 h of usage.

In practice, these devices are frequently used without specialised blankets with warm air blowing directly onto the patient. Filters are often not replaced, according to the manufacturer's recommendations (Augustine Medical).

We set out to determine whether these devices blow contaminated air. Thereafter, we sought to ascertain whether the use of perforated blankets could prevent the detection of such contamination. We further tried to locate possible sites of contamination. Finally, we sought to establish whether placing a microbial filter on the end of the hose of the warming devices might filter out organisms.

Methods

A vascular operating theatre, which is cleaned daily with Bacterex-C® (disinfectant cleaner containing organic chloride and detergent compounds), was chosen as the site of the experiments. Operating theatre temperature ranged between 21 and 23 °C and humidity between 61 and 67%. The investigators wore full operating theatre clothes and sterile gloves and remained at a distance of at least 1 m from the equipment for the duration of the experiments. Agar plates were on sterile towels on the operating table.

Experiment 1: are microbes present in the air stream of warmers?

Ten intra-operative patient warming devices (nine Bair Huggers, Augustine Medical, and one Warm Touch, Mallinckrodt Medical) were assessed. Each warmer was placed sequentially on a standard place on the floor. The nozzle of the hose was suspended from an infusion stand 40 cm above two agar plates. The machine was turned on to blow air at 43 °C over the plates for 5 min. There was a break of 5 min between each machine. Control plates were placed at the beginning and end of the experiment with no warmer blowing.

Experiment 2: do perforated blankets reduce microbial contamination?

Two of the warmers which had yielded early growth on agar plates were assessed further. The warmers were attached to infusion stands. Perforated blankets were elevated over agar plates. The warmers were set to blow air at 43 °C through the blankets over the plates for 30 min. Control plates were placed under a blanket for 30 min without air blowing. Warmed air was also blown directly onto agar plates as had been done in Experiment 1.

Experiment 3: can colonisation be localised?

Three of the warmers whose agar plates had grown organisms were swabbed from both sides of the internal microbial filter and from the inside of the hose at its proximal (warmer) and distal (patient) ends.

Experiment 4: can contamination of the air stream be reduced?

The same three warmers were set to blow onto agar plates for 5 min with and without microbial filters fitted to the distal ends (nozzles) of their hoses. The filters used were DAR Hygrobac Filters for breathing systems (DAR S.p.A). These serve as both bacterial and viral filters.

Microbiology methods

Two agar plates were used to sample warmed air from each machine. One contained dextrose agar with chloromycetin (DAC) and the other 5% horse blood agar. Following completion of each experiment, each plate was wrapped in laboratory film. Swabs and plates were transported to the laboratory immediately, where swabs were plated onto DAC and 5% horse blood agar. The plates were incubated at 37 °C and inspected every 2 days for growth. Blood plates were kept for a total of 7 days and DAC plates for 1 month before being called negative. Visible colonies growing on the plates were picked off and identified according to standard bacteriological and fungal laboratory procedures.

Results

Experiment 1: microbes are present in the air streams of warmers (Table 1)

There was a pure growth of *Aspergillus fumigatus* on both control plates. Organisms grew on plates from four of the 10 (40%) warmers. The organisms cultured were *Staphylococcus xylosus* (from two plates), *S. epidermidis* (from one plate), *Corynebacterium* spp. (from one plate) and *Cryptococcus albidus* (from one plate). *A. fumigatus* was also isolated from two of the test plates.

Experiment 2: perforated blankets reduce microbial contamination (Table 2)

The control plates grew no organisms. The agar plates directly in the stream of the warmers both grew

Table 1 Microbes present in the air streams of warmers.

Machine type	Number	Hours in use	Usual theatre	Organisms cultured
Bair Hugger 500E	1		general surgery	none
Bair Hugger 500E	2		neurosurgery	none
Bair Hugger 505	3	245.6	cardiac surgery	*Corynebacterium* spp.
Bair Hugger 505	4	426.2	paediatric surgery	none
Bair Hugger 505	5	111.1	paediatric surgery	*Staphylococcus xylosus, Aspergillus fumigatus*
Bair Hugger 505	6	157.7	recovery room	none
Bair Hugger 505	7	112.9	paediatric surgery	none
Bair Hugger 505	8	666.2	general surgery	*Cryptococcus albidus, A. fumigatus, S. xylosus*
Bair Hugger 505	9	718.5	general surgery	none
Warm Touch 500	10		cardiac surgery	*S. epidermidis*
Control 1				*A. fumigatus*
Control 2				*A. fumigatus*

Table 2 Microbial contamination with and without the use of perforated blankets.

Machine number	Method used	Organisms cultured
5	Under blanket for 30 min	none
5	In direct air stream for 5 min	*S. epidermidis* and *Corynebacterium* spp.
8	Under blanket for 30 min	none
8	In direct air stream for 5 min	*S. epidermidis*
Control	Under blanket for 30 min without warm air blowing through	none

Table 3 Sites of colonisation in three warmers.

Machine number	Site of swab	Organisms cultured
3	inside of filter	none
3	outside of filter	*Staphylococcus aureus*
3	proximal hose	*Corynebacterium* spp.
3	distal hose	*S. epidermidis, Corynebacterium* spp.
5	inside of filter	none
5	outside of filter	*S. epidermidis, Aspergillus niger, A. fumigatus*
5	proximal hose	*Bacillus* spp.
5	distal hose	none
8	inside of filter	none
8	outside of filter	*S. epidermidis, Bacillus* spp., *A. niger*
8	proximal hose	*Corynebacterium* spp., *A. fumigatus*
8	distal hose	*A. fumigatus*

organisms (*S. epidermidis* in two and one additionally grew a *Corynebacterium* spp.). Those which had warm air blown on them through the perforated blankets grew no organisms.

Experiment 3: microbial colonization of warmers is detected (Table 3)

Swabs from the outer surfaces of the filters from three warmers grew *Staphylococcus aureus, S. epidermidis, A. fumigatus, Aspergillus niger* and *Bacillus* spp. None of the swabs from the inner surfaces grew organisms. The proximal hose swabs grew *Corynebacterium* spp., *Bacillus* spp. and *A. fumigatus*. The distal hose swabs grew *S. epidermidis, Corynebacterium* spp. and *A. fumigatus*.

Table 4 Contamination with and without a microbial filter attached to the nozzle of the hose of the warmer.

Machine number	Method used	Organisms cultured
3	blowing through filter	none
3	direct blowing	*Acinetobacter lwoffii*
5	blowing through filter	none
5	direct blowing	*Staphylococcus epidermidis*
8	blowing through filter	none
8	direct blowing	*S. epidermidis*

Experiment 4: a microbial filter attached to the nozzle of the hose reduces contamination (Table 4)

Plates placed directly in the air streams of the three warmers grew *Acinetobacter lwoffii* and *S. epidermidis*. When microbial filters were fitted to the nozzles of the same warmers, there was no growth.

Discussion

Infection control is of paramount importance to all practitioners, particularly at a time when multidrug resistant organisms are emerging. We have detected a potential source of nosocomial infection at our hospital. The filters in convection warmers (when replaced regularly) should protect against entrained bacterial and fungal pathogens, but may not prevent colonisation in the machines distal to the filters.

Our results indicate that, when air was sampled directly from the warming devices (without the use of the recommended perforated blankets), microbial pathogens were detectable in almost half of the devices tested. When the experiment was repeated with the use of the recommended blankets, contamination of sampled air (through the blankets) was no longer detected.

Organisms cultured in the experiments are typical of skin flora (*S. epidermidis, S. xylosus, A. lwoffii* and *Corynebacterium* spp.) or are ubiquitous organisms present in the

environment (*A. fumigatus*, *A. niger*, *Bacillus* spp. and *C. albidus*). These organisms are potentially pathogenic, especially in immunocompromised patients and when prosthetic devices are present (e.g. indwelling central lines, heart valves).

Following this study, we have altered policy in our hospital. We now ensure that forced air convection warmers are only used when attached to perforated blankets. We also recommend that microbial filters be changed as specified by the manufacturer and that detachable hoses are sterilised regularly. A microbial filter fitted to the nozzle of the hose could be incorporated into the design of the warmer to reduce the risk of contamination.

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